Consumer behavior indicates broadcast drug ads have positive health benefits.

Evaluating the Welfare Effects of Drug Advertising

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IN AUGUST OF 1997, THE FOOD AND DRUG Administration changed the rules for the broadcast of direct-to-consumer advertising (DCA) of prescription drugs. There is a clear divide in public policy circles over the consequence of this change. Many groups assert that DCA puts physicians under pressure to prescribe drugs unnecessarily. Other groups argue that DCA can inform people about conditions they might not know they have or about treatments they might not know exist—effects that would improve health outcomes. Obviously, it is important to evaluate the claims of each group in order to implement effective policy.

At this writing, the FDA is conducting a review of its DCA policy. Unfortunately, there is little relevant research for the agency to draw upon. In particular, there is relatively little DCA research that has been done on what we believe could best inform FDA policy: analysis of detailed, patient-level clinical data that track changes in actual behavior.

In this article, we will review the history of direct-to-consumer drug advertising and the theoretical arguments for and against it. We will also critique DCA research that focuses on survey results and advertising content analysis. We will then present a review of our own research. Our research, we believe, is precisely the sort that is required: evaluations of detailed, patient-level information, using cases that allow us to say something directly about the effect of DCA on patient well-being.

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DCA OVERVIEW

For most of the world, DCA for prescription drugs is a nonissue. Both the European Union and Canada, for example, officially prohibit the practice. Only New Zealand and the United States sanction DCA. The market for DCA is most advanced in the United States, where such promotion has been used, at least in some part, for over 30 years.

As the practice grew in the United States, the FDA requested a voluntary moratorium on drug ads in 1982 until it could issue guidelines. Those guidelines were released in 1985, and simply asserted that pharmaceuticals should adhere to the same rules that govern drug advertising to physicians. That meant that the ads must include the product generic name, a brief list of side effects and contra-indications, the ads must relate only material facts, and they must not be false or misleading.

In practice, drug makers and the FDA interpreted the regulations to also hold that broadcast ads could not mention both the name of the product and its clinical benefits in the same ad. For example, an early television advertisement for Claritin gave the name of the product but did not inform consumers that it is a non-drowsy treatment for hay fever.

The prohibition on offering a drug's brand name and clinical benefits in the same ad ended in August of 1997 when the FDA issued new guidelines with respect to broadcast DCA. Since that time, DCA on television and radio has been permitted to reveal both the name of the product and its clinical benefit, as long as "adequate provision" is made to fully inform the consumer of side effects and contra-indications via a toll-free telephone number, Web address, or reference to a complete print advertisement.

Figure 1 shows the trend in mass-media DCA spending since 1989. Interestingly, the figure shows that the rise in DCA began before the August 1997 regulatory change. This suggests that the FDA decision to ease its regulations should be understood as a reaction to a change in DCA behavior rather than the sole cause of the change.

One phenomenon that is hidden in the series is the sharp increase since 1995 in the proportion of DCA that is targeted at television as compared to radio and print media. In 1994, for example, television ads accounted for only 13.5 percent of all DCA promotion; by 2000 that proportion had risen to 63.8 percent.

ECONOMIC ARGUMENTS

The beginnings of the current policy debate on DCA may date to the 1985 *New England Journal of Medicine* article "Matching Prescription Drugs and Consumers" by Alison Masson and Paul Rubin. The article makes several points about the merits of consumer advertising for pharmaceuticals. First, advertising can help consumers to realize that they suffer from an undiagnosed medical condition. For example, thanks to an ad campaign by Pfizer, many people who had been experiencing persistent thirst may have learned that thirst is a symptom of diabetes. Drug advertising also provides information about new treatments to consumers who suffer from diagnosed medical conditions. These effects are probably the two most-cited benefits of DCA by supporters of drug advertising.

One of the recurring themes among critics of DCA is concern that the practice could intrude on the agency relationship between physicians and patients. Fundamentally, the issue has merit—if patients hire physicians with superior medical knowledge to make decisions regarding diagnoses and treatment, what new information can be added by DCA? The problem with this criticism is that because there are few comprehensive models of physician/patient interactions concerning prescribing, we know very little about the efficiency of such agency relationships, with or without DCA. Thus, observing that DCA tends to increase prescribing is uninformative (from a welfare perspective) unless we know that prescribing was optimal prior to DCA.

We note, however, that the traditional marketing alternative to DCA, "detailing," comes with its own set of agency problems. Detailing involves representatives of pharmaceutical companies coming to physicians' offices and encouraging physicians to prescribe their products. Generally, these visitors bring with them free samples for physicians to give to their patients. "Cooperative" physicians may also receive other perquisites from pharmaceutical companies, such as free trips to pleasant resorts. Thus, while DCA could involve some distortion of the agency relationship between physicians and patients, it is difficult to conclude that such distortion would obviously be worse than the distortion brought about by detailing.

ADVERTISING AND PRICES One complaint against drug advertising is relatively easy to refute. Various critics have asserted that the costs associated with DCA will be recouped through higher prices. This argument is problematic because it fails to model firms as profit-maximizers in a competitive

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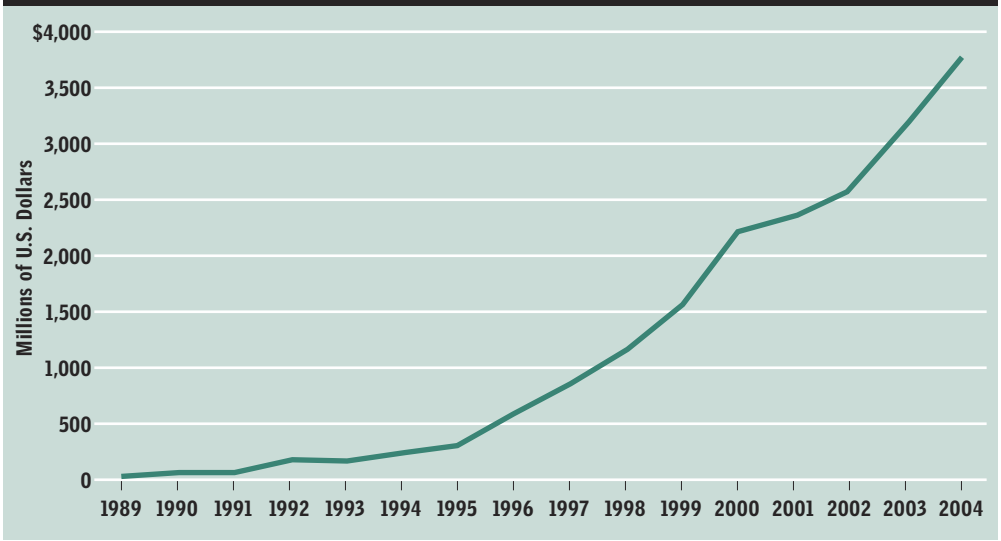
FIGURE 1

Spending on U.S. Direct-to-Consumer Drug Advertising

(1989-2004)



industry. Firms seek to market their products in the most cost-effective way possible. Thus, if DCA is more effective at the margin than detailing or other forms of marketing (or, even, with no marketing at all), then firms will use DCA, and doing so will reduce, not increase, firm costs.

THE STATE OF THE DEBATE

Researchers attempting to determine the value of DCA have generally used three types of evaluative methods: surveys, advertising content analysis, and consumption pattern analysis. Below, we consider the results of each of these methods.

SURVEYS There are a number of articles that use survey data to analyze the impact of DCA. The articles can be divided into two categories: those that examine patient sentiments about DCA and those that examine physician sentiments.

With respect to patients, the articles indicate that younger patients, patients with chronic health conditions, and parents of children with health conditions are positively disposed toward DCA. Older patients, however, appear more likely to ignore DCA and rely more heavily on their physicians. Survey results also indicate that physicians quite often prescribe something other than what their patients, perhaps driven by DCA, suggest.

The results with respect to physicians are also mixed. Survey articles show that more experienced physicians, physicians with larger caseloads, and physicians with more exposure to DCA are likely to be supportive of such advertising. Survey results, however, also show physicians were quicker to become annoyed with repeated patient questioning when the reason was DCA compared to patients who got their information from medical publications. This negative attitude reinforces results from earlier survey studies, which found that nearly 80 percent of physicians had a negative attitude toward DCA and that a large percentage of patients would react negatively (either expressing disappointment or seeking a new physician) if they were denied a prescription that they asked about after having seen it advertised.

We have serious qualms about the use of survey data for policy considerations. Surveys can tell us what people believe about certain issues and can give us information about their demand for particular consumer products. However, they do not appear to be terribly useful for answering the fundamental question: Does DCA change actual behavior or improve health outcomes?

CONTENT ANALYSIS Another type of research on DCA ads involves examining the content of the ads themselves. This analysis tries to determine whether or not such ads are "fair and balanced." But this seems an odd test; by its very nature, advertising is not supposed to be fair and balanced. Rather, it is intended to promote the product in question. Yet, of all the different types of product advertising, pharmaceutical ads may be the least promotional: All pharmaceutical ads contain a (relatively) long discussion of the potential negative side effects of the relevant drug. Regardless, we suggest that consumers in the United States are well aware that advertisements—including drug ads—are one-sided in nature.

CONSUMPTION There are only a limited number of studies of DCA that use actual patient data. One of the first, a 2002 study by John Calfee, Clifford Winston, and Randolph Stempski, examines whether the 1997 FDA policy change increased the demand for the statin class of drugs. Their regressions are based on aggregate monthly data on drug usage for a 58-month period. Interestingly, the authors are unable to find any statistically significant short-run direct effect on aggregate prescriptions filled. According to the authors, "it may only be possible to detect the effect of DCA on consumer demand with disaggregated data that link a patient's cholesterol treatment history with the timing of DCA expenditures."

Three other studies have used such data to explore the effect of DCA. In 2002, Woodie Zachry and colleagues used the National Ambulatory Medical Care Survey, along with national frequencies of advertising for a number of drug classes, to examine frequencies of monthly prescribing for the time period 1992–1997. While they find some significant relationships, the effects are not consistent. More recently, Julie Donohue and colleagues published a study in 2004 of approximately 31,000 patients that examined how likely patients were to use antidepressants when they were diagnosed in months with high spending on DCA compared to

those who were diagnosed during months with low DCA spending. They found that advertising for any brand of antidepressant medication tended to increase the use of all brands—though the impact was small. Finally, a 2005 study by Marta Wosinska examined the likelihood that patients with high cholesterol complied with treatment recommendations for statin therapy. Similar to the work of Donohue and others, she found small class-level effects.

With the exception of the last study, no work to date has been able to address directly whether any observed changes in behavior from DCA is likely to be improving economic efficiency. Thus, our recent work may be able to help fill in this missing piece of the puzzle.

OUR RESEARCH

In our research (conducted with Steven Ornstien and Paul Neitert of the Medical University of South Carolina), we have examined an important patient population: people with osteoarthritis. This is a widespread and debilitating disease, and drug therapy is one of the main approaches to alleviating osteoarthritis pain and suffering.

Cox-2 inhibitors—one of the drug classes used for treating arthritis pain—have been at the center of much recent public debate over DCA. There are two main Cox-2 inhibitors, Vioxx and Celebrex, both of which were heavily advertised in recent years. Both of the drugs have since been discovered to increase the risk for serious cardiovascular conditions, and Vioxx was withdrawn from the market in 2004 for this reason.

We believe that these drugs present an ideal opportunity to study the effect of DCA. They were heavily promoted; they were believed to have potentially serious side effects, but the side effects were only widely discussed after the drugs were on the market and advertised. If we are able to find any positive welfare effects from DCA ads for this drug class, then that would suggest that policymakers would want to take great care in broadly restricting the practice—at least without much further, careful study.

To conduct our study, we obtained data on patients from nearly 90 primary care practices scattered across the United States. The data contain all the information one would usually find in clinical charts, including details of diagnoses, vital statistics, and detailed prescription histories. We pulled all of the osteoarthritis patients out of the data and examined how their prescribing patterns were correlated with national and local DCA spending over the 2000–2002 time period. We also collected information on television advertising spending for Vioxx and Celebrex for each month in 75 media markets. (Patients and physicians were linked to the closest media market.)

Our analysis consists of regression models, which we use to explain three dependant variables. The first is the number of osteoarthritis patients who visited a doctor's office each month. This is designed to tell us whether the hypothesis that DCA prompts patients to seek care is supported. The second regression model explains the number of prescriptions for Vioxx and Celebrex that physician practices wrote each month. This tells us whether there was a change in overall prescribing. Finally, the third regression model explains how long patients wait after they have been diagnosed with osteoarthritis before they start using either Vioxx or Celebrex. This last model is the most direct test of whether DCA improves or harms social welfare.

Our first set of models yields clear answers to the question of if patients respond to DCA by visiting their doctor. We find that advertising for both Vioxx and Celebrex increased the number of patients with osteoarthritis who got office visits each month. This effect is consistent across many ways of specifying the model.

The second set of models indicates some interesting dynamics at the market level—though they are a little less easy to interpret. We find that the number of Vioxx prescriptions rose in communities or months where there was more advertising for Vioxx and Celebrex. In that sense, the ads had class level effects: advertising for any brand tended to increase the use of Vioxx. However, the results for Celebrex prescribing are different. Neither Vioxx nor Celebrex DCA spending seems to have had an effect on Celebrex prescribing. Again, these results are stable across our models. There are other ways, however, that DCA can be expected to affect prescribing use other than raw counts of the number of prescriptions written by each practice each month.

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HEALTH EFFECTS These two practice-based studies indicate that DCA advertising has an effect at the macro-level. However, this leaves open the issue of whether DCA-induced changes are good for patients or not. For that, we need to conduct an analysis of patient decisions rather than practice-level changes.

To explore this issue, we collected patient-level data and asked how long patients delayed after being diagnosed with osteoarthritis before they started using Vioxx or Celebrex as daily therapy for their symptoms. This is an important question because clinical guidelines suggest a number of steps that should be taken before osteoarthritis patients start daily Cox-2 inhibitor therapy. For example, patients should try changes

to their exercise and diet, or should try less powerful, over-the-counter pain medicines. So, some delay is optimal.

We also know that some patients are better candidates than others for using Vioxx or Celebrex. In particular, when patients have gastrointestinal side effects from some pain medications, then they are likely to benefit from the special nature of the Cox-2 inhibitors. If DCA provides real information, the ads would encourage those patients to adopt Vioxx or Celebrex sooner than patients would otherwise. We can identify which patients fall into this class.

In contrast, there are some patients who clearly are poor candidates for Vioxx or Celebrex. We now know that patients with cardiovascular disease or hypertension are at higher risk for adverse cardiovascular events and should try many other options before resorting to Vioxx or Celebrex for their osteoarthritis symptoms. But this information was only widely discussed after the August 2001 publication of a crucial article in the clinical literature. So our second test of whether DCA provides real information is to see whether more advertising encouraged patients with cardiovascular risk factors to adopt Vioxx or Celebrex later than they otherwise would. However, as an added wrinkle, if it is a DCA information effect, this increased delay should occur only after August 2001.

So, if DCA spending is moving patients in the right direction, we should see that patients in communities or time periods with more DCA spending, and who have gastrointestinal difficulties, should adopt Vioxx or Celebrex more rapidly. We should also see patients in communities or time periods with more DCA spending and who have cardiovascular problems adopting Vioxx or Celebrex less rapidly—but only after August of 2001.

This is a fairly specific test. And, when we estimate our models, this is exactly the pattern we see. Greater amounts of any Cox-2 inhibitor advertising encouraged gastro patients to adopt sooner for all time periods. On the other hand, greater amounts of any Cox-2 inhibitor DCA before August 2001 encouraged cardiovascular disease patients to adopt sooner. But after August 2001, when the adverse effects of Cox-2 inhibitors became widely known, greater amounts of any Cox-2 inhibitor DCA encouraged cardiovascular disease patients to adopt later. It is hard to imagine another mechanism—other than provision of real information—that would account for this pattern.

Our patient-level analyses are remarkably consistent and clear. DCA advertising for Vioxx and Celebrex did affect prescribing behavior, and did so in exactly the direction an objective social advocate would want. Good candidates for the drug received it sooner, poor candidates received it later. Thus, our results imply that Vioxx and Celebrex television ads actually improved the matching of therapy to patient.

In summary, we are able to state the following: Television DCA for Vioxx and Celebrex had the effect of encouraging patients to see their physicians. At an aggregate level, the DCA affected the rate of prescribing for at least one of our study drugs; and for the average patient, television DCA in this time period seemed to improve matching patients to treatments.

CONCLUSION

DCA has become a significant feature of the U.S. health care system. Contrary to common opinion, there are many reasons to expect that drug advertising can improve the flow of information.

We have studied the effect of DCA on a drug class, Cox-2 inhibitors, that has been one of the most controversial over the past decade. For those drugs, we find that the net effect of DCA is to get patients in front of their physicians and to improve the matching of patients to treatment. Thus, DCA has at least some positive effect on social welfare.

We view our results, however, as a little light in a very dark place. Much more research at the patient level needs to be done to understand the impact of DCA. Our research, however, does suggest that that DCA can provide important pro-consumer impacts. R

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